

Attorney Docket No.: LP-31004-US

PATENT

IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

INTERNATIONAL APPLICATION NO. PCT/DK04/000573

US APPLN. SER. NO. : 10/569862

INTERNATIONAL FILING DATE: 30 August 2004

PRIORITY DATE: 29 August 2003

TITLE: MODIFIED RELEASE COMPOSITIONS COMPRISING
TACROLIMUS

APPLICANT(S) FOR RO/US: HOLM, Per and NORLING, Tomas

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with 37 C.F.R. 1.56, 1.97 and 1.98, Applicants submit herewith references which they believe may be material to the patentability of this application and with respect to which there may be a duty to disclose in accordance with 37 C.F.R. 1.56.

While the references may be "material" under 37 C.F.R. 1.56, it is not intended to constitute an admission that the references are "prior art" unless specifically designated as such.

The filing of this Information Disclosure Statement shall not be construed as a representation that no other material references than those listed exist or that a search has been conducted.

The references are listed in PTO form 1449 which is in accordance with the requirements of M.P.E.P. 609. A copy of the references is also enclosed.

The references are as follows:

U.S. Patent Documents

Yamanaka et al., US Patent No. 6,387,918 B2, issued May 14, 2002

Foreign Patent Documents

Pharotech A/S WO 03/004001 A1, published January 16, 2003*

Lipocine, Inc. WO 01/37808 A1, published May 31, 2001*

Fujisawa Pharmaceutical Co., LTD EP 1 064 942 A1, published January 3, 2001*

Fujisawa Pharmaceutical Co., LTD EP 0 444 659 A2, published September 4, 1991

Fujisawa Pharmaceutical Co., LTD EP 0 184 162 A2, published June 11, 1986

Other Documents

Nishi et al., 2004, "The colon displays an absorptive capacity of Tacrolimus", Transplantation Proceedings, vol. 36, no. 2, pp. 364-366.*

Nishi et al., 2004, "The expression of intestinal CYP3A4 in the Piglet Model", Transplantation Proceedings vol. 36, no. 2, pp. 361-363.*

Sano et al., 2002, "Oral FK 506 blood levels are elevated in pig short bowel model: Further investigations with co-administration of an intestinal CYP3A4 inhibitor" Transplantation Proceedings vol. 34, no. 3, pp. 1050-1051.*

Honbo et al., 1987, "The oral dosage form of FK-506", Transplantation Proceedings, vol. 19, no. 5 supplement 6, pp. 17-22.*

It is respectfully requested that these references be considered by the Patent and Trademark Office in its examination of the above-identified application and be made of record therein. The Examiner is also invited to contact the Undersigned if there are any questions concerning this paper or the attached references.

The Information Disclosure Statement submitted herewith is being filed

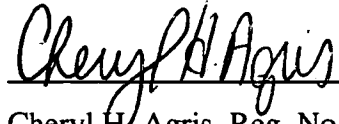
☒ before the mailing date of a first Office Action on the merits

☐ after the mailing date of a first Office Action on the merits. Please charge the fee of \$180 to credit card. Form PTO-2038 is attached.

☒ An International Search Report is enclosed. References cited in the International Search report are asterisked.

Date: 6/13/06

Respectfully submitted,



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| Substitute for form 1449/PTO <div style="text-align: center; font-weight: bold; font-size: 1.2em;"> INFORMATION DISCLOSURE STATEMENT BY APPLICANT </div> <div style="text-align: center; font-style: italic; font-size: 0.8em;"> (Use as many sheets as necessary) </div> | | <div style="text-align: center; font-weight: bold; font-size: 1.1em;"> Complete if Known </div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td>10/569862</td> </tr> <tr> <td>Filing Date</td> <td>February 27, 2006</td> </tr> <tr> <td>First Named Inventor</td> <td>Holm</td> </tr> <tr> <td>Art Unit</td> <td>TBD</td> </tr> <tr> <td>Examiner Name</td> <td>TBD</td> </tr> <tr> <td>Attorney Docket Number</td> <td>LP-31004-US</td> </tr> </table> | | Application Number | 10/569862 | Filing Date | February 27, 2006 | First Named Inventor | Holm | Art Unit | TBD | Examiner Name | TBD | Attorney Docket Number | LP-31004-US |
| Application Number | 10/569862 | | | | | | | | | | | | | | |
| Filing Date | February 27, 2006 | | | | | | | | | | | | | | |
| First Named Inventor | Holm | | | | | | | | | | | | | | |
| Art Unit | TBD | | | | | | | | | | | | | | |
| Examiner Name | TBD | | | | | | | | | | | | | | |
| Attorney Docket Number | LP-31004-US | | | | | | | | | | | | | | |

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| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|-----------------------|---|------------------|---|---|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear | T ⁶ |
| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | MM-DD-YYYY | | | |
| M.Y./ | | WO 03/004001 A1 | 01-16-2003 | Pharotech A/S | | |
| M.Y./ | | WO 01/37808 A1 | 05-31-2001 | Lipocine, Inc. | | |
| M.Y./ | | EP 1 064 942 A1 | 01-03-2001 | Fujisawa ... Co. LTD | | |
| M.Y./ | | EP 0 444 659 A2 | 09-04-1991 | Fujisawa ... Co. LTD | | |
| M.Y./ | | EP 0 184 162 A2 | 06-11-1986 | Fujisawa ... Co. LTD | | |
| M.Y./ | | | | | | |

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|-----------------------|---------------------------------|--------------------|------------|
| Examiner Signature | /Micah Paul Young/ (10/21/2009) | Date Considered | 10/21/2009 |
|-----------------------|---------------------------------|--------------------|------------|

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

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|------------------------|-------------------|
| Application Number | 10/569862 |
| Filing Date | February 27, 2006 |
| First Named Inventor | Holm |
| Art Unit | TBD |
| Examiner Name | TBD |
| Attorney Docket Number | LP-31004-US |

Sheet 1 of 1

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|--------------------|-----------------------|---|----------------|
| /M.Y./ | | NISHI et al., 2004, "The colon displays an absorptive capacity of Tacrolimus", Transplantation Proceedings, vol. 36, no. 2, pp. 364-366.* | |
| /M.Y./ | | NISHI et al., 2004, "The expression of intestinal CYP3A4 in the Piglet Model", Transplantation Proceedings vol. 36, no. 2, pp. 361-363.* | |
| /M.Y./ | | SANO et al., 2002, "Oral FK 506 blood levels ..." Transplantation Proceedings vol. 34, no. 3, pp. 1050-1051.* | |
| /M.Y./ | | HONBO et al., 1987, "The oral dosage form of FK-506", Transplantation Proceedings, vol. 19, no. 5 supplement 6, pp. 17-22.* | |
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| Examiner Signature | /Micah Paul Young/ (10/21/2009) | Date Considered | 10/21/2009 |
|--------------------|---------------------------------|-----------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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